and MTG patients. Additionally, hospitalizations in intensive care units (50% SG vs. 22% MTG patients), emergency visits (21% SG vs. 6% MTG) and the presence of adenoma complications (73% SG vs. 44% MTG) constitute a source of cost increment in these patients. Patients who accomplish with the most strict study clinical control criteria (GH < 1.0 and IGF-1 < 100%) showed the lowest direct cost of illness (€6169 vs. €12,990). **CONCLUSIONS:** The economic cost of acromegaly is dependent on the clinical control of the disease. Direct cost of illness is the half that the cost in non controlled patients.

PDB85

APPROVAL AFTER REJECTION—AN INSIGHT IN HTA RE-EVALUATIONS

Sweeney N, Andreykiv M, Wiebinga C

Quintiles Consulting, Hoofddorp, The Netherlands

OBJECTIVES: To gain insight into the re-evaluation process of HTA agencies after an initial rejection and identify the adaptations that led to the approval of re-submitted dossiers. **METHODS:** Phase I: manual search of 57 health care agencies' websites for published diabetes-related assessments (January 2007-May 2010). Phase II: the two most re-assessed drugs for which detailed information was available were selected for further evaluation (insulin glargine and exenatide). For these drugs, all reports published prior to 2007 were also included. **RESULTS:** Phase I identified 117 relevant single technology appraisals; 18 were re-evaluations. Six agencies performed re-evaluations of the same drug after an initial rejection: CADTH, CVZ, HAS, PBAC, AHTAPol and SMC. To date, SMC evaluated 32 submissions for 13 anti-diabetic drugs, PBAC published 20 (eight drugs), CADTH 13 (four drugs), CVZ 14 (four drugs) and AHTAPol 10 (two drugs). In phase II insulin glargine (four re-submissions to PBAC and 1 to CADTH) and exenatide (two re-submissions to PBAC, 1 to CVZ and 1 to AHTAPol) were evaluated. It became clear that payers do focus on overall cost. The approach that was chosen for those two drugs was to control overall cost either by restricting access or by settling on a lower price. CVZ accepted exenatide for reimbursement only after restricting access to a subgroup of obese type 2 diabetes mellitus patients (with an ICER of €5.231). Instead of patient segmentation PBAC insisted on lowering the price for both medications (rationale for insulin glargine being concern that prescribing cannot be contained within the defined population). AHTAPol limited exenatide reimbursement to 50% to control prescribing rates. **CONCLUSIONS:** For the diabetes cases analyzed HTA agencies attempted to control health care expenditure by either lowering drug costs or by narrowing the definition of the target population, the latter inevitably allowing fewer patients access to the drug.

PDB86

HEALTH TECHNOLOGY ASSESSMENT OF DIABETES COMPOUNDS: THE POLISH PERSPECTIVE

Adalsteinsson JE[1], Czech M[2], Skrekowska-Baran I[3], Jasik BM[1]

[1]Novo Nordisk A/S, Copenhagen, Denmark; [2]Department of Pharmacoeconomics, Medical University of Warsaw, Warsaw, Poland; [3]Novo Nordisk Pharma Sp, Warszawa, Poland

OBJECTIVES: The AOTM in Poland was established to give MoH in Poland advice on reimbursement. The aim of this research is to create an overview of HTA reports on diabetes compounds in Poland and the results of the decision making. **METHODS:** A search was conducted on the webpage of AOTM (http://www.aotm.gov.pl) for HTA reports on the following products: Rosiglitazon, Pioglitazon, Sitagliptin, Vildagliptin, Saxagliptin, Exenatide, Liraglutide, Glargine, Detemir, Aspart, Glulisene and Lispro. **RESULTS:** Of a total of 163 reports (published between 2007 and 2010), eight reports in Polish language on diabetes were identified and assessed. Two reports can be viewed as secondary assessment of regulatory safety discussions. The other six reports assessed the implementation of new diabetes compounds with assessment of efficacy, safety and cost-effectiveness of the drugs.Two reports assessed safety concerns associated with the risk of cancer and concluded based on EMA and FDA research that no increased risk was associated with these agents. Rosiglitazone and Sitagliptin were not recommended for reimbursement due to availability of other treatments with similar efficacy. Saxagliptin, Exenatide and Liraglutide got the recommendation to be reimbursed due to expected increase in QALYs. The final report was assessing Glulisene which got the recommendation to temporary reimburse (2 years) provided that data on hard endpoints (not specified in public report) and cost-effectiveness should be delivered. **CONCLUSIONS:** Recommendation by AOTM is supported by assessment of available RCTs, cost per life-year gained, cost per QALY, estimated budget impact for 5 years and also in some cases reports from EMEA, FDA and other HTA agencies (SMC, PBAC and CADTH). The AOTM's recommendation is not obligatory for the Polish Ministry of Health.

PDB87

STANDARDS FOR THE ASSESSMENT OF ANTIDIABETIC DRUGS—THE IQWIG PERSPECTIVE

Schweikert B[1], John J[2], Ringborg A[3], Erhardt W[4], Bleckmann A[5], Neubauer AS[4]

[1]i3 Innovus, Aschheim, Germany; [2]Helmholtz Zentrum München, Neuherberg, Germany; [3]i3 Innovus, Stockholm, Sweden; [4]Bristol-Myers Squibb, München, Germany; [5]AstraZeneca, Wedel, Germany

OBJECTIVES: A substantial number of new pharmaceutical treatment strategies have been introduced for the treatment of diabetes mellitus type II. The availability of these drugs for patients in different countries depends on the evaluation standards and methods applied in the various phases of drug assessment. Objective of this research was to review the requirements and criteria applied for the assessment of antidiabetic drugs along the regulatory process by EMA (Europe) and FDA (USA) for the assessment of efficacy and safety as well as for reimbursement decisions by NICE (England) and IQWiG (Germany) and to compare their consistency, with a special focus on IQWiG's procedures. **METHODS:** A review of relevant current method documents and reports on evaluations of antidiabetic drugs published by IQWiG was conducted. These were compared with guidance documents issued by FDA, EMA and NICE with respect to endpoints considered in diabetes and their definition, criteria for the type of evidence, and potential comparators. **RESULTS:** Consistently, across all agencies severe and non-severe hypoglycemias were considered highly relevant. There was, however, a substantial heterogeneity in the definition of hypoglycaemias. The surrogate parameter $HbA1_C$ as primary endpoint was accepted by all agencies investigated apart from IQWiG. In its assessments, evidence from randomized as well as from observational studies was accepted by NICE. For safety evaluations preclinical studies were taken into consideration by EMA and FDA in addition to randomized controlled trials. IQWiG on the other hand focused exclusively on randomized controlled trials for the assessment of effectiveness as well as safety. **CONCLUSIONS:** There is a substantial variation of criteria applied and evidence considered relevant within the assessment process of IQWiG compared to other agencies. This might lead to regional variations in the availability of drugs. It is important to be aware of the different requirements of agencies, when designing trials and planning market access.

PDB88

LEARNING FROM DISEASE MANAGEMENT PROGRAMMES: HOW MEDICAL TREATMENTS AND QUALITY OF DIABETIC CARE (TYPE II) IN GERMANY ARE DIRECTLY AND INDIRECTLY IMPROVED BY DMPS

Frenzel A[1], Reuter A[2]

[1]IMS Health GmbH & Co. OHG, Frankfurt, Germany; [2]Freie Universität Berlin, Berlin, Germany

OBJECTIVES: Disease Management Programmes (DMP) aim at improving care quality by implementing standards for medical practices. In the case of Diabetes Mellitus Type II (DM II), care improvements can be assessed by the duration between the first diagnosis and the occurrence of the first related complication. The aim of this longitudinal study is to investigate the direct influence of the DMP-based treatments on patient outcomes, measured as the postponement of diabetes related complications in a large population of DM II patients. The study also investigates how DMP inscriptions of some patients of a medical practice indirectly influence patient outcomes of DM II patients, who are not inscribed in a DMP, but are treated in the same practise. We argue that this indirect effect is due to physicians' learning from the DMP-based treatments in their clinics. **METHODS:** Using consultation data from IMS Health from a period of 25 years (1984–2009) a survival analysis is applied. The data set includes 161,747 DM II patients from >1100 practices. Applying a Kaplan–Meier–Method we test for direct effects of DMPs on patient outcomes. By pooling patients by the registration year of the practice-leading physician and by focussing on their quarterly consultation rate, we test for indirect effects of DMPs on patient outcomes. **RESULTS:** The mean survival time (duration between first diagnosis and first complication) of the medical treatment of diabetics in a DMP is 14,82 years, differing significantly from the 15,76 years without a DMP. These tests are controlled for following patient variables: sex, age, HbA1C, BMI and the insurance status. Learnings from DMPs, indirectly affecting DM care, significantly postpone complications for younger physicians and practices with fewer diabetics. **CONCLUSIONS:** Contributing to assessments of DMPs, the study discusses policy implications, as it is shown that care quality is improved by physicians learning from DMPs.

PDB89

PREDICTORS OF ROUTINE MONITORING OF DIABETES CARE AMONG THE US NON-INSTITUTIONALIZED POPULATION: A RETROSPECTIVE ANALYSIS OF THE MEDICAL EXPENDITURE PANEL SURVEY (MEPS) IN 2007

Zhao Y, Fonseca V, Campbell C, Shi L

Tulane University, New Orleans, LA, USA

OBJECTIVES: To examine the rate and predictors of diabetes monitoring in the US. **METHODS:** This cross-sectional retrospective study was conducted on a representative, non-institutionalized sample of the US population, using the self-reported information from the 2007 Household Component (HC) of the MEPS. According to the American Diabetes Association (ADA) 2007 practice guidelines, proper provider monitoring is defined as at least two A1c tests, one eye and one foot examination annually. Health status was measured by SF-12®Version2. a logistic regression model was used to examine the predictors of proper monitoring. Differences in health status and medical expenditures between patients with and without proper monitoring were examined using t-tests. Estimates were weighted to the total population (WTP). **RESULTS:** Among 1,747 (WTP: 19,320,394) patients with diabetes, 80.64% had at least two A1c tests; 63.29% had an eye examination; and 67.51% had a foot examination. Thus, 63.36% patients (WTP: 14,065,289) received proper diabetes monitoring. Older patients (OR:1.021, 95% confidence interval [CI]: 1.012–1.030), non-Hispanic Caucasians compared with African American patients (OR: 1.236, 95% CI: 0.933–1.636), patients with a higher education level (OR:1.211, 95% CI: 1.056–1.390), insurance coverage (OR:2.216, 95% CI: 1.408–3.486), use of oral anti-diabetic drugs (OR:2.935, 95% CI: 2.131–4.042) and insulin (OR:3.453, 95% CI: 2.477–4.814) were more likely to undergo the proper monitoring. Well monitored patients had a higher Mental Component Summary score (50.09 ± 0.37 vs. 48.51 ± 0.45, $P < 0.05$), but a lower Physical Component Summary score (39.95 ± 0.34 vs. 42.28 ± 0.47, $P <$